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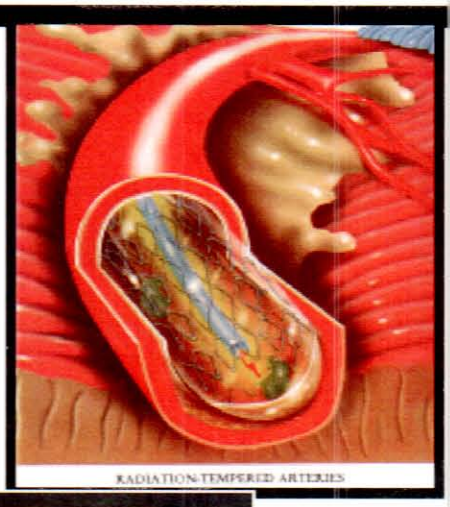
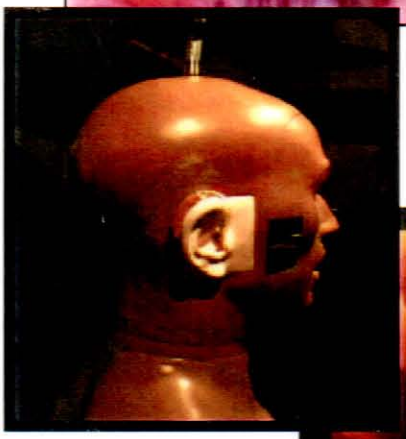
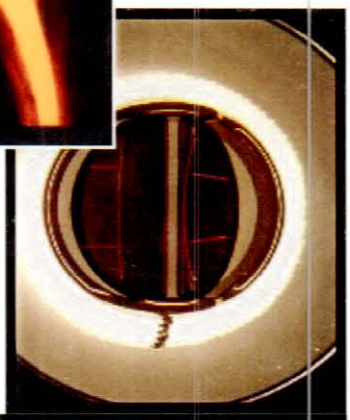
NISTIR 6791

Workshop on Standards for Biomedical Materials and Devices

June 13 - 14, 2001







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Workshop on Standards for Biomedical Materials and Devices

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Technology Administration
National Institute of Standards
and Technology
Gaithersburg, MD 20899-8230

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U.S. DEPARTMENT OF COMMERCE
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NATIONAL INSTITUTE OF STANDARDS
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Harmonization of Standards

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Overview

Harmonization of standards means development and use of a single standard that is universally acceptable to all affected parties. Ideally, this will include compatibility with worldwide requirements of both government and industry. Drivers for harmonization include the emergence of a global market affecting both trade and travel, extensive regulation for the biomedical industry (sometimes with conflicting regulations and supporting standards), and a growing body of diverse information that standards can help to make uniform. To be effective, harmonized standards must be globally accepted, technically correct, practical, responsive to regulatory needs, and readily accessible.

Why should standards be harmonized? Because **not** harmonizing is too expensive. Harmonization avoids the duplication of effort required to develop multiple standards. Multiple standards on the same topic waste resources, are confusing to the users, can be expensive to conform to, and are generally burdensome. Hence, as such standards arise from different sources, harmonization is needed as a continuing process toward reducing them to one standard for all applications. The resulting harmonized standard must have global acceptance. If the harmonized standard is developed by an international organization, such as ISO and IEC, it will typically have quick global acceptance. When the standard is used in a regulatory application, regulators, not just in the United States, but also around the world, must also be encouraged to cite it. Finally, it must be used by the market, that is, by manufacturers, suppliers, and customers around the world.

In the development of harmonized standards, the ideal standards process should adhere to the principles of due process. It should be open, balanced, and involve all parties who have an interest in a particular area. During the process, participants should consider the market relevance and any particularly appropriate clinical relevance of the intended standard. The resulting standard should also be timely, flexible and efficient, both in terms of initial development and on-going maintenance.

Despite all the benefits of standardization, the standards process is often criticized as too political, too slow and tedious, or too easily dominated by a single interest so that all voices aren't heard. Other concerns relate to lack of adequate funding, particularly for ensuring participation of academic, consumer, or other diverse interests in a consensus process. Finally, there is concern that the resulting standard, being based in consensus, may be below the lowest acceptable common denominator, because too many compromises have been made. Despite these criticisms, the harmonized standard still remains the best way to meet market needs in both health and safety, as well as in trade and manufacturing.

To achieve a harmonized standard, interested parties must determine if a standard(s) already exists and they may have to conduct pre-standardization research to resolve technical problems before attempting to standardize procedures or test methods. They must find and work through an appropriate sponsoring standards development organization (SDO) toward a consensus standard. Often validation of the standard will require round robin testing to ensure that it will, in fact, produce the desired results.

In all of these steps, NIST can play an important role to facilitate the development and the use of harmonized standards.

Proposed Roles for NIST in Harmonizing of Standards.

- Challenge the underlying technical assumptions, such as "sterilization is under control" (when, in fact, discussion at this workshop indicated that sterilization of TEMPs remains a complex problem that needs to be solved).
- Conduct pre-normative research on technical issues so that the path to harmonized global standards is smoothed.
- Develop sound test methods for particular topics in conjunction with industry and government agencies, to meet the needs of both.
- Assist in the verification of proposed test methods so that the standards developed using those test methods are valid and reliable.
- Facilitate not only the development, but also the use, of harmonized standards.
- Consider developing a database of all existing biomedical standards worldwide and their reference in regulations to enable interested parties to determine the need for new standards quickly.
- Provide (or continue to provide) an open forum for discussion of industry and government needs in standards.
- Educate important stakeholders on the value of standards and the need for participation in developing sound, harmonized standards.
- Ensure that NIST staff participates at the technical level in processes that will result in internationally accepted standards.
- Look for gaps and disharmony in the standards development process and alert stakeholders. To achieve the roles laid out for NIST above, NIST will need more funding for scientific participation in the standards process, including biomedical standards.

In conclusion, NIST must develop a formal, ongoing and continuing working mode with industry sectors that involves SDOs and regulatory authorities when appropriate.